

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in August 2003.

New Approvals

NADA Number: 141-040

Trade Name:	Celerin TM		
Ingredients:	Estradiol benzoate		
Sponsor:	PR Pharmaceuticals, Inc.		
Approval Date:	June 25, 2003		
Status:	Over-the-counter		
Route:	Subcutaneous (ear only)		
Species:	Cattle: steers and heifers fed in confinement.		
Drug Form:	Powder, liquid (suspension)		
Concentration:	20 milligrams per milliliter		
Indications:	For increased rate of weight gain and improved feed efficiency in steers and in heifers which will not be used for reproduction.		
Tolerance:	21CFR 556.240 Estradiol: No residues of estradiol are permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated animals; in the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion for muscle, 480 parts per trillion in fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver.		
Withdrawal:	Zero days		
Patent Number:	5,288,496	Expiration date:	February 22, 2011
	5,401,507		March 28, 2012
	5,427,796		February 22, 2011
Exclusivity:	3 years		

21CFR 522.841 & 510.600

NADA Number: 141-041

Trade Name:	Celerin™ C		
Ingredients:	Estradiol benzoate		
Sponsor:	PR Pharmaceuticals, Inc.		
Approval Date:	June 25, 2003		
Status:	Over-the-counter		
Route:	Subcutaneous (ear only)		
Species:	Cattle, suckling beef calves		
Drug Form:	Powder, liquid (suspension)		
Concentration:	10 milligrams per milliliter		
Indications:	For increased rate of weight gain in calves at least 30 days old which will not be used for reproduction and not used for veal.		
Tolerance:	21CFR 556.240 Estradiol: No residues of estradiol are permitted in excess of the following increments above the concentrations of estradiol naturally present in untreated animals; in the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion for muscle, 480 parts per trillion in fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver.		
Withdrawal:	Zero days		
Patent Number:	5,288,496	Expiration date:	February 22, 2011
	5,401,507		March 28, 2012
	5,427,796		February 22, 2011
Exclusivity:	3 years		

21CFR 522.841 & 510.600

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: [141-204](#)

Trade Name: Sentinel® Flavor Tabs®, Capstar® Tablets, Flea Management System™
Ingredients: Milbemycin oxime/lufenuron, nitenpyram
Sponsor: Novartis Animal Health US
Approval Date: June 11, 2003
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Tablets
Concentration: Sentinel® Flavor Tabs® : 2.3 milligrams milbemycin oxime/ 46 milligrams lufenuron, 5.75 milligrams milbemycin oxime/ 115 milligrams lufenuron, 11.5 milligrams milbemycin oxime/ 230 milligrams lufenuron, and 23 milligrams milbemycin oxime/ 460 milligrams lufenuron per tablet.
 Capstar® Tablets (nitenpyram): 11.4 and 57 milligrams per tablet.
Indications: For use in dogs 4 weeks and older to kill adult fleas and to prevent flea eggs from hatching.
Exclusivity: 3 years

21CFR 520.1446 & 520.1510

NADA Number: [141-205](#)

Trade Name: Program® Flavor Tabs®, Capstar™ Tablets, Flea Management System™
Ingredients: Lufenuron, nitenpyram
Sponsor: Novartis Animal Health US
Approval Date: June 11, 2003
Status: Over-the-counter
Route: Oral
Species: Dogs and cats
Drug Form: Tablets
Concentration: Program® Flavor Tabs® (lufenuron): 45, 90, 204.9, and 409.8 milligrams per tablet
 Capstar™ Tablets (nitenpyram): 11.4 and 57 milligrams per tablet.
Indications: For use to kill adult fleas and to prevent flea eggs from hatching.
Exclusivity: 3 years

21CFR 520.1288 & 520.1510

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: [141-216](#)

Trade Name: Quest[®] Plus Gel
Ingredients: Moxidectin, praziquantel
Sponsor: Fort Dodge Animal Health, Division of Wyeth
Approval Date: May 14, 2003
Status: Over-the-counter
Route: Oral
Species: Horses and ponies
Drug Form: Gel
Concentration: 20 milligrams moxidectin and 125 milligrams praziquantel per milliliter
Indications: For the treatment and control of the following stages of gastrointestinal parasites of horses and ponies six months of age and older and not to be used for food:
Large strongyles: *Strongylus vulgaris* (adult and L₄/L₅ arterial stages), *Strongylus edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *Triodontophorus serratus* (adults)
Small strongyles: *Cyathostomum* spp. (adults), *Cyathostomum catinatum* (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated luminal larvae
Encysted cyathostomes: Late L₃ and L₄ mucosal cyathostome larvae
Ascarids: *Parascaris equorum* (adults and L₄ larval stages)
Pinworms: *Oxyuris equi* (adults and L₄ larval stages)
Hairworms: *Trichostrongylus axei* (adults)
Large-mouth stomach worms: *Habronema muscae* (adults)
Horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars), *Gasterophilus nasalis* (3rd instars)
Tapeworms: *Anoplocephala perfoliata* (adults)
Patent Number: 4,916,154 Expiration date: April 10, 2007
Exclusivity: 3 years

21CFR 520.1453

ANADA Number: [200-315](#)

Pioneer Product: 034-025
Trade Name: Lincomycin 25, Lincomycin 100, Lincomycin 300
Ingredients: Lincomycin hydrochloride
Sponsor: Veterinary Laboratories, Inc.
Approval Date: April 2, 2003
Status: Over-the-counter
Route: Intramuscular
Species: Swine
Drug Form: Liquid (solution)
Concentration: 25, 100, and 300 milligrams per milliliter
Indications: For the treatment of infectious arthritis and mycoplasma pneumonia.
Tolerance: 21CFR 556.360 Lincomycin: Tolerances for residues in swine is 0.6 part per million in liver and 0.1 part per million in muscle.
Withdrawal: 2 days

21CFR 522.1260

Actions Taken by FDA Center for Veterinary Medicine

Supplemental Approvals

NADA Number: [141-035](#)

This supplemental application provides for labeling changes reflecting the concurrent use with Capstar® (nitenpyram) Tablets (NADA 141-175) and reflecting a decrease in the minimum age from 6 weeks to 4 weeks.

Trade Name: Program® Flavor Tabs™
Ingredients: Lufenuron
Sponsor: Novartis Animal Health US, Inc.
Approval Date: June 11, 2003
Status: Over-the-counter
Route: Oral
Species: Dogs, cats
Drug Form: Tablet
Concentration: 45 milligrams, 90 milligrams, 204.9 milligrams, and 409.8 milligrams
Indications: **Dogs:** For the prevention and control of flea populations in dogs and puppies six weeks of age and older.
Cats: For the control of flea populations in cats and kittens six weeks of age or older.
Patent Number: 4,798,837 Expiration Date: January 31, 2006
5,153,224 October 6, 2009
5,416,102 May 30, 2012
5,420,163 May 30, 2012
Exclusivity: 3 years

21CFR 520.1288

NADA Number: [141-084](#)

This supplemental application provides for labeling changes reflecting the concurrent use with Capstar® (nitenpyram) Tablets (NADA 141-175).

Trade Name: Sentinel® Flavor Tabs®
Ingredients: Milbemycin oxime, lufenuron
Sponsor: Novartis Animal Health US, Inc.
Approval Date: June 11, 2003
Status: Prescription only
Route: Oral
Species: Dogs
Drug Form: Tablet
Concentration: 2.3 milligrams milbemycin oxime/ 46 milligrams lufenuron, 5.75 milligrams milbemycin oxime/ 115 milligrams lufenuron, 11.5 milligrams milbemycin oxime/ 230 milligrams lufenuron, and 23 milligrams milbemycin oxime/ 460 milligrams lufenuron per tablet.
Indications: For the prevention of heartworm disease caused by *Dirofilaria immitis*, the prevention and control of flea populations, the control of adult *Ancylostoma caninum* (hookworm), and the removal and control of adult *Toxocara canis*, *Toxascaris leonina* (roundworm) and *Trichuris vulpis* (whipworm) infections. Do not use in dogs weighing less than two pounds or younger than four weeks of age.
Patent Number: 4,547,520 Expiration Date: June 14, 2004
5,994,395 January 23, 2018
Exclusivity: 3 years

21CFR 520.1446

Actions Taken by FDA Center for Veterinary Medicine

NADA Number: [141-175](#)

This supplemental application provides for labeling changes reflecting the concurrent use with Program® (lufenuron) Flavor Tabs® (NADA 141-035) and Sentinel® (milbemycin oxime/lufenuron) Flavor Tabs® (NADA 141-084).

Trade Name:	Capstar™
Ingredients:	Nitenpyram
Sponsor:	Novartis Animal Health US, Inc.
Approval Date:	June 11, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Dogs, cats, puppies, kittens
Drug Form:	Tablet
Concentration:	11.4 milligrams and 57 milligrams
Indications:	For the treatment of flea infestations in dogs, cats, puppies, and kittens four weeks or older.
Patent Number:	5,750,548
Exclusivity:	3 years
	Expiration date: April 29, 2016

21CFR 520.1510

NADA Number: [141-199](#)

This supplemental application provides for use of carprofen solution by subcutaneous injection for the control of postoperative pain associated with soft tissue and orthopedic surgeries.

Trade Name:	Rimadyl® Injectable
Ingredients:	Carprofen
Sponsor:	Pfizer, Inc.
Approval Date:	April 2, 2003
Status:	Prescription only
Route:	Subcutaneous
Species:	Dogs
Drug Form:	Liquid (solution)
Concentration:	50 milligrams per milliliter
Indications:	For the relief of pain and inflammation associated with arthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries.
Exclusivity:	3 years

21CFR 522.312

Actions Taken by FDA Center for Veterinary Medicine

ANADA Number: [200-346](#)

This supplemental application provides for an additional (higher) dose for use in feedlot steers.

Pioneer Product: 140-992
Trade Name: Component® TE-200
Ingredients: Trenbolone acetate, estradiol
Sponsor: Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date: April 21, 2003
Status: Over-the-counter
Route: Subcutaneous
Species: Cattle (steers fed in confinement for slaughter)
Drug Form: Implant (ear only)
Concentration: 10 pellets with each containing 20 milligrams trenbolone acetate and 2 milligrams estradiol.
Indications: For increased rate of weight gain and improved feed efficiency.
Tolerance: *21CFR 556.240* Estradiol: Residues for estradiol and related esters may not exceed the following increments above the concentration of estradiol naturally present in untreated animals: In the uncooked edible tissues of heifers, steers, and calves: 120 parts per trillion in muscle, 480 parts per trillion in fat, 360 parts per trillion in kidney, and 240 parts per trillion in liver.
21CFR 556.739 Trenbolone: A tolerance for total residues in uncooked edible tissues is not needed.
Withdrawal: Zero days

21CFR 522.2477

Addition of Sponsor

PR Pharmaceuticals, Inc.
1716 Heath Parkway
Fort Collins, CO 80524
Drug Labeler Code: 067210

Correction of a Final Rule

The Final rule published in the *Federal Register* of June 19, 2003 FDA is correcting the amount of monocalcium phosphate in the formula for a free-choice, loose mineral Type C medicated feed containing lasalocid. In the table in Sec. 558.311 Lasalocid in paragraph (e)(4)(i), in the row for "Monocalcium Phosphate" the entry in the "Percent" column is corrected from 57.50 to read "57.70".

Correction to the January 1, 2003 list of the Green Book

The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the approved status of a new animal drug application (NADA) held by Pennfield Oil Co. FDA is also publishing a proposed rule to remove certain obsolete or redundant sections of the new animal drug regulations. That proposed rule contains background information about those regulations and also for this action.
Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, drug labler code 053389 holds an approval for NADA 138-934 for use of PENNCHLOR SP 250 and PENNCHLOR SP 500 (chlortetracycline, procaine penicillin, and sulfamethazine) three-way, fixed combination Type A medicated articles to make three-way combination drug Type C medicated swine feeds for use for growth promotion, increased feed efficiency, and the management of several bacterial diseases. This product is subject to the transitional approval provision of section 108(b)(2) of the Animal Drug Amendments of 1968 and is currently subject to interim marketing under Sec. 558.15(g)(1) (21 CFR 558.15(g)(1)). At this time, 21 CFR 558.145 is being amended to reflect this approved application.

Actions Taken by FDA Center for Veterinary Medicine

Products Subject to a Notice of Hearing

The Food and Drug Administration (FDA) is announcing the effective conditions of use for certain drug products and use combinations in the following four categories: Bacitracin methylene disalicylate single-ingredient Type A medicated articles, oxytetracycline and neomycin fixed-combination Type A medicated articles, and combination drug Type B and Type C medicated feeds for poultry containing bacitracin. The agency is also proposing to withdraw the new animal drug applications (NADAs) for those products or use combinations lacking substantial evidence of effectiveness, following a 90-day opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the agency is providing an opportunity for hearing. Elsewhere in this issue of the Federal Register, FDA is publishing a proposed rule to remove certain obsolete or redundant sections of the new animal drug regulations where these subject drug products and use combinations are listed. That proposed rule contains background information about those regulations and also for this action.

Submit written request for a hearing and appearance by September 8, 2003. Submit all data and analysis upon which a request for a hearing relies by October 7, 2003. Submit supplemental NADAs by November 6, 2003.

Under Section 512(c)(2)(A)(ix) of the Federal Food, Drug, and Cosmetic Act an abbreviated new animal drug application cannot be approved if, among other reasons, the approved new animal drug is the subject of a published Notice of Hearing. These products may not be copied:

Nada Number	Tradename	Sponsor
141-137	Fortracin MD 50 Type A Medicated Article	Pennfield Oil Co.
094-975	Neo-Terramycin	Phibro Animal Health
138-939	Neo-Oxy	Pennfield Oil Co.
098-371	Nicarbazin, Penicillin G Procaine, and 3-Nitro	Phibro Animal Health
098-374	Nicarbazin and Penicillin GProcaine	Phibro Animal Health
100-853	Nicarbazin, Baciferm, and 3- Nitro	Phibro Animal Health
141-130	BMD and Zoalene	Alpharma, Inc.
141-131	BMD, zoalene, and roxarsone	Alpharma, Inc.
141-132	Zinc bacitracin and nitarosone	Alpharma, Inc.